UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/488,164	06/07/95	KOPCHICK J	7707-015

001444
BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON DC 20001-5303

HM12/0522

EXAMINER	
SAOUD, C	
ART UNIT	PAPER NUMBER
1647	28

DATE MAILED: 05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev.11/00)

1- File Copy

Office Action Summary

Application No.	Applicant(s)
08/488,164	KOPCHICK et al.
Examiner	**Art Unit**
Christine Saoud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 29, 2000* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *10-45, 62, .63, and 65-106* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *10-45, 62, 63, and 65-106* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Claims 10, 29, 35, 46, 26, 34, 30-32, 33, 38, 64, 63, 19-24, 39 have been amended and claims 75-106 have been added as requested in the amendment of paper #24, filed 28 July 2 2000. Actually, since claims 46 and 64 were previously canceled, these amendments do not apply to them (see paper #25). Applicant's response of 29 November 2000 is noted, but is moot in light of the new restriction presented below.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 10-44, 62, 65-87, 99-106 drawn to DNA molecules, classified in at least class 530, subclass 300, for example.

II. Claim 45, drawn to a transgenic animal, classified in at least class 514, subclass 800.

III. Claims 63, 88-98 drawn to methods of gene therapy, classified in at least class 514, subclass 44.

3. Inventions I and (II-III) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA molecules of Group I could be used in either of

Groups II or III, therefore, the product could be used in a materially different process (i.e. either of Groups II or III, or further, in a recombinant method of protein production).

4. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together in that the animal of Group II is not required for Group III, and the method of Group III is not used for the animal of Group II.

In addition to the broad restriction of DNA molecules, transgenic animal and methods above, the claims are drawn to a multitude of patentably distinct DNA molecules and methods of using a multitude of patentably distinct proteins. The DNA molecules are directed to those encoding proteins. The prior art recognizes that a single amino acid difference in proteins by definition gives a new protein (see Robson et al. Introduction to Proteins and Protein Engineering, page 41, Elsevier, 1986). Therefore, each DNA molecule encoding a protein encompassed by the instant claims are considered patentably distinct. For instance, claim 23 requires amino acids from growth hormone, prolactin, placental lactogen, or other hormones; claims 75-79 encompass specific amino acid substitutions; claim 34 recites particular functions, etc.. Therefore, restriction within Groups I-III is required because the claims are drawn to numerous patentably distinct DNA molecules or encompass the use of numerous patentably distinct DNA molecules, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention (i.e. DNA molecule) having a specific molecular embodiment.

Applicants should note that in some cases multiple claims encompass one of the patentably distinct inventions set forth herein. To be fully responsive to this requirement, Applicants are **required** to point out which claims correspond to the elected invention.

Although the classifications for these various nucleic acids are overlapping, for instance 536/23.5, each represents a patentably distinct product with distinct physical and functional characteristics, as indicated by the limitations of the claims reciting particular functions and physical characteristics. Further the search for more than one product would be burdensome because each product has a distinct structure and function. Accordingly, restriction is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 37 C.F.R. § 1.48(b) and by the fee required under 37 37 C.F.R. § 1.17(i).

Conclusion

It is suggested to Applicant that the claims are so complex and written in such a confusing manner, that a complete and meaningful examination is very difficult. It is noted that claims to a DNA molecule encoding a growth hormone variant comprising an amino acid substitution corresponding to position 119 of bovine growth hormone, wherein the growth hormone variant has growth hormone inhibitory activity, appears to be free of the prior art of record and would be enabled by the instant specification as filed. If Applicant were to elect the protein, once an

allowable product is found, Applicant would be entitled to examination of method claims limited to the allowable product (i.e. same scope). Applicant should note that are a number of issues regarding the enablement of gene therapy claims, and allowable methods claims cannot be indicated at this time. Applicant should note that issues of new matter, enablement and written description which have been previously raised would be obviated by the above language, if the claims were so limited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 21, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud